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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

CHATTOPADHYAY, URMI

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 08/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/775,677

Applicant(s)

SOLEM ET AL.

Examiner

Urmi Chattopadhyay

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 May 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14-17, 22, 25-27, 30, 32-40 and 74-85 is/are pending in the application.
- 4a) Of the above claim(s) 25-27, 32-36 and 74 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 14-17 is/are allowed.
- 6) ☒ Claim(s) 22, 30, 37-40 and 75-85 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 2/7/05, 5/4/05
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

Response to Amendment

1. The amendment filed 5/20/05 has been entered. The changes to the claims have been approved. New claims 75-85 have been added. Claims 14-17, 22, 25-27, 30, 32-40 and 74-85 are currently pending, of which claims 25-27, 32-36 and 74 remain withdrawn from consideration for being drawn to a non-elected species. The claims being considered for further examination on the merits are claims 14-17, 22, 30, 37-40 and 75-85.

Information Disclosure Statement

2. The information disclosure statements (IDSs) filed on 2/7/05 and 5/4/05 have been considered by the examiner. A signed and initialed copy of each PTO-1449 is enclosed.

Claim Rejections - 35 USC § 101

3. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 77 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. By claiming the elongate body to have "at least two first segments fixed to an interior wall of the coronary sinus", the interior wall of the coronary sinus is a claimed element of the invention. Because the interior wall of the coronary sinus is a part of the body, it is not statutory subject matter. The examiner suggests inserting --adapted to be-- before "fixed" on line 4.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 22, 30, 37-40, 75-82, 84 and 85 are rejected under 35 U.S.C. 103(a) as being unpatentable over Imran (USPN 5,817,126, as cited in applicant's IDS) in view of Orth et al. (USPN 5,591,197).

Imran discloses a medical device and medical system for remodeling an extravascular tissue structure adjacent to a vessel/body space in a patient and an apparatus with all the elements of claims 22, 38, 40, 75, 76 and 77, but is silent to the elongate body being adapted to exert a force from within the coronary sinus onto the mitral valve annulus in order to remodel the mitral valve annulus. See Figure 1 for a medical device (10) comprising an elongate body (11) extending between a proximal end (24) and a distal end (44), and that is adjustable from a first configuration having a first shape such that the elongate body is adapted to be delivered at least in part into the vessel/body space to a second configuration having a second shape (column 1, lines 18-24). See column 3, lines 26-43 for the dimensions of the elongate body (11) being within ranges that would allow for it to be inserted into and positioned in the first configuration at least in part within a coronary sinus. See Figure 1 for the distal end (44) of the elongate body (11) being spaced distally from the proximal end (24) of the elongate body (11) in the first and second configurations. See columns 6-7, lines 65-3 for a deployment system cooperating with the elongate body (11) and being adapted to and capable of at least in part delivering the elongate

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body (11) in the first configuration to the coronary sinus. See column 3, lines 54-56 for the elongate body comprising a memory material (nitinol). See Figure 1 and columns 3-4, lines 63-1 for the elongate body (11) having at two first segments (20, 40) and a second segment (60) disposed between the first segments (20, 40). See column 6, lines 35-37 for the second segment (60) being capable of decreasing its axial length to draw one of the first segments towards the other first segment.

Orth et al. teaches a stent (10) that forms barbs upon expansion for contacting and penetrating the vessel wall in order to anchor and affix the stent thereto. See column 1, lines 8-9, column 3, lines 33-35 and column 7, lines 45-47. It would have been obvious of one of ordinary skill in the art to look to the teachings of Orth et al. to modify the elongate body (11) of Imran by having the two first segments (20, 40) be barb forming stents in order for the barbs to contact and penetrate the vessel wall. This will anchor and affix the stent to the vessel wall and prevent migration of the stent. When the first segments (20, 40) are expanded and affixed to the coronary sinus wall, subsequent expansion of the second segment (60) will reduce a longitudinal length of a portion of the coronary sinus by drawing one of the first segments attached to a first portion of the coronary sinus towards the other first segment attached to a second portion of the coronary sinus. See column 5, lines 62-65. This will cause the elongate body (11) to exert a force from within the coronary sinus onto the mitral valve annulus and remodel the mitral valve annulus without fully encircling the mitral valve annulus.

Claim 30, see column 2, lines 30-32 for the flexibility of the second segment (60) permitting the elongate body (11) to define an arc shape in the second configuration.

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Claims 37 and 78, see rejection to claim 77, *supra*. By drawing one of the first segments attached to a first portion of the coronary sinus towards the other first segment attached to a second portion of the coronary sinus by expanding the second segment (60), the elongate body (10) will compress the mitral valve annulus to thereby reduce the diameter of the space while inhibiting a portion of the coronary sinus from lengthening.

Claim 39, see columns 6-7, lines 65-3 for the deployment system comprising a delivery member (deployment catheter) coupled to the elongate body (11) and adapted to and capable of advancing the elongate body (11) into the coronary sinus.

Claim 79, see column 6, lines 35-37 for the second segment (60) decreasing in axial length as the second segment (60) is expanded in a radial direction.

Claim 80, see column 6, lines 1-4 for each of the first segments (20, 40) being configured to expand in a radial direction without substantial length reduction.

Claim 81, see Figure 2 and column 6, lines 1-4 for the first segments (20, 40) comprising a plurality of radially expandable cells, each of which radially expand without substantial length reduction.

Claim 82, see column 6, lines 22-39 for each segment being capable of independent expansion.

Claim 84, see Figure 1 and column 3, lines 15-17 for the elongate body (10) being a stent.

Claim 85, see column 3, lines 54-56 for the elongate body (10) being made of a memory material (nitinol).

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6. Claim 83 is rejected under 35 U.S.C. 103(a) as being unpatentable over Imran and Orth et al. as applied to claim 77 above, and further in view of Lunn (USPN 5,876,433).

Imran, as modified by Orth et al., discloses an apparatus with all the elements of claim 77, but is silent to the additional limitation of the elongate body being coated to avoid thrombosis in the coronary sinus, as required by claim 83. Lunn teaches coating a stent with heparin in order to reduce thrombosis. See column 1, lines 25-27 and column 2, lines 44-47. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to the teachings of Lunn to modify the stent of Imran and Orth et al. by coating the stent with heparin in order to avoid thrombosis. When the stent is implanted into the coronary sinus, the heparin coating will increase the possibility of reducing thrombus in the coronary sinus.

Allowable Subject Matter

7. Claims 14-17 are allowed.

Response to Arguments

8. Applicant's arguments with respect to claims 22, 30, 37-40 and 75-85 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

9. The art made of record and not relied upon is considered pertinent to applicant's disclosure. Alferness et al. (USPN 6,908,478) discloses that anchoring two anchors within the

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coronary sinus and then reducing the space between the two anchors remodels the mitral valve annulus.

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Urmi Chattopadhyay whose telephone number is (571) 272-4748. The examiner can normally be reached on Tuesday-Thursday 10:00am - 6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'Urmi Chattopadhyay', with a stylized, looping flourish at the end.

Urmi Chattopadhyay

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